IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Appellant: Mohan Krishnan et al.
Title: ENDOCARDIAL LEAD FOR A LEFT HEART CHAMBER

Docket No.:	279.650US1	Serial No.:	10/731,421
Filed:	December 9, 2003	Due Date:	December 21, 2008
Examiner:	Joseph Stoklosa	Group Art Unit:	3762
Customer No.:	45458	Confirmation No.:	3925

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

We are transmitting herewith the following attached items (as indicated with an "X"):

X Appeal Brief (20 pgs.)
X Authorization to charge Deposit Account 19-0743 in the amount of $540.00 to cover the fee for the Appeal Brief
X Return Postcard

Please charge any additional fees or credit overpayment to Deposit Account No. 19-0743.

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
Customer No.: 45458

By: _____
Peter C. Maki
Reg. No. 42,832

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Appeal Brief - Patents Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 10 day of December, 2008.

Nicole Jack
Name

Signature

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of: Mohan Krishnan et al. Examiner: Joseph A. Stoklosa

Serial No.: 10/731,421 Group Art Unit: 3762

Filed: December 09, 2003 Docket: 279.650US1

For: ENDOCARDIAL LEAD FOR A LEFT HEART CHAMBER

APPEAL BRIEF UNDER 37 CFR § 41.37

Mail Stop Appeal Brief- Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

The Appeal Brief is presented in response to the Notice of Panel Decision from Pre-Appeal Brief Review mailed on November 21, 2008 and further in support of the Notice of Appeal to the Board of Patent Appeals and Interferences, filed on September 15, 2008, from the Final Rejection of claims 1, 5, 7 and 9-18 of the above-identified application, as set forth in the Final Office Action mailed on June 25, 2008.

The Commissioner of Patents and Trademarks is hereby authorized to charge Deposit Account No. 19-0743 in the amount of $540.00 which represents the requisite fee set forth in 37 C.F.R. § 41.20(b)(2). The Appellants respectfully request consideration and reversal of the Examiner's rejections of pending claims.

APPEAL BRIEF UNDER 37 C.F.R. § 41.37

TABLE OF CONTENTS

1. REAL PARTY IN INTEREST

The real party in interest of the above-captioned patent application is the assignee, CARDIAC PACEMAKERS, INC..

2. RELATED APPEALS AND INTERFERENCES

There are no other appeals or interferences known to Appellant that will have a bearing on the Board's decision in the present appeal.

3. STATUS OF THE CLAIMS

The present application was filed on December 9, 2003 with claims 1-23. During prosecution claim 24 was added and claims 5, 6, and 21-24 were cancelled. Claims 2, 3, 4, 8, 19, and 20 are presently withdrawn. A Final Office Action (hereinafter "the Final Office Action") was mailed June 13, 2008. Claims 1, 5, 7 and 9-18 stand twice rejected, remain pending, and are the subject of the present Appeal.

4. STATUS OF AMENDMENTS

No amendments have been made subsequent to the Final Office Action dated June 13, 2008

5. SUMMARY OF CLAIMED SUBJECT MATTER

Aspects of the present inventive subject matter include, but are not limited to, an endocardial lead for a left heart chamber.

INDEPENDENT CLAIM 1

1. A lead comprising:

a lead body (102) extending from a proximal end to a distal end; (Figs 1 and 2; page 2, lines 19-20) and

a ring electrode (216) coupled to the lead body; (Fig 3; page 3, lines 25-26)

wherein the lead body and the ring electrode each have an outer surface adapted to passively prevent formation of clots on the outer surfaces, wherein the outer surface (210) (Fig. 3; page 3, lines 26-27) of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, (Page 4, lines 17-21; page 5, lines 12-21; Page 5, lines 22-28; page 6, lines 3-8; page 6, lines 9-20) and wherein the outer surface of the ring electrode includes a textured coating including titanium microspheres. (Page 5, lines 1-10).

DEPENDENT CLAIM 7

7. The lead of claim 1, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent blood cell layer. (Page 5, lines 1-9).

INDEPENDENT CLAIM 11

11. A lead comprising:

a lead body (102) extending from a proximal end to a distal end; (Figs 1 and 2; page 2, lines 19-20) and

a ring electrode (216) coupled to the lead body; (Fig 3; page 3, lines 25-26)

wherein the lead body has a textured outer surface (510) adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface; (Fig 5; page 6, lines 3-20) and

wherein the ring electrode includes an outer textured surface including titanium microspheres. (Page 5, lines 1-10).

DEPENDENT CLAIM 12

12. The lead of claim 11, wherein the electrode outer surface is adapted to trap blood cells within the textured surface to form a layer of blood cells on the electrode surface. (Page 5, lines 1-9).

DEPENDENT CLAIM 15

15. The lead of claim 11, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface. (Page 5, lines 1-9).

INDEPENDENT CLAIM 17

17. A lead comprising:

a lead body (102)extending from a proximal end to a distal end; (Figs 1 and 2; page 2, lines 19-20)

a ring electrode (216) coupled to the lead body; (Fig 3; page 3, lines 25-26) and

means for passively preventing formation of clots on the ring electrode and the lead body, wherein means for passively preventing clots on the ring electrode includes a titanium microsphere outer surface coating on at least a portion of the ring electrode, (Page 5, lines 1-10) and wherein means for passively preventing clots on the lead body includes forming the lead body such that a layer of blood cells is formed on an outer surface of the lead body when exposed to a bloodstream. (Page 4, lines 17-21; page 5, lines 12-21; Page 5, lines 22-28; page 6, lines 3-8; page 6, lines 9-20).

DEPENDENT CLAIM 15

18. The lead of claim 17, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface. (Page 5, lines 1-9).

This summary does not provide an exhaustive or exclusive view of the present subject matter, and Appellant refers to each of the appended claims and its legal equivalents for a complete statement of the invention.

6. GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

Claims 1, 5, 7 and 9-18 were rejected under 35 U.S.C. § 103(a) as being unpatentable over Helland et al. (U.S. Patent No. 5,318,572).

7. ARGUMENT

A) The Applicable Law under 35 U.S.C. §103

The Examiner has the burden under 35 U.S.C. § 103 to establish a prima facie case of obviousness. *In re Fine*, 837 F.2d 1071, 1074, 5 USPQ2d 1596, 1598 (Fed. Cir. 1988). To do that the Examiner must show that some objective teaching in the prior art or some knowledge generally available to one of ordinary skill in the art would lead an individual to combine the relevant teaching of the references. *Id.*

The Fine court stated that:

> Obviousness is tested by "what the combined teaching of the references would have suggested to those of ordinary skill in the art." *In re Keller*, 642 F.2d 413, 425, 208 USPQ 871, 878 (CCPA 1981)). But it "cannot be established by combining the teachings of the prior art to produce the claimed invention, absent some teaching or suggestion supporting the combination." *ACS Hosp. Sys.*, 732 F.2d at 1577, 221 USPQ at 933. And "teachings of references can be combined only if there is some suggestion or incentive to do so." *Id.*

The M.P.E.P. adopts this line of reasoning, stating that

> In order for the Examiner to establish a *prima facie* case of obviousness, three base criteria must be met. First, there must be some suggestion or motivation, either in the references themselves or in the knowledge generally available to one of ordinary skill in the art, to modify the reference or to combine reference teachings. Second, there must be a reasonable expectation of success. Finally, the prior art reference (or references when combined) must teach or suggest all the claim limitations. The teaching or suggestion to make the claimed combination and the reasonable expectation of success must both be found in the prior art, and not based on Appellant's disclosure. M.P.E.P. § 2142 (citing *In re Vaeck*, 947 F.2d 488, 20 USPQ2d 1438 (Fed.Cir. 1991)).

B) Discussion of the rejection of claims 1, 5, 7 and 9-18 which were rejected under 35 U.S.C. § 103(a) as being unpatentable over Helland et al. (U.S. Patent No. 5,318,572).

Claims 1, 5, 7, 9, and 10

Appellant traverses the obviousness rejection of claim 1. Appellant believes claim 1 is not obvious in view of the Helland reference since the reference does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the Helland reference: wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, as recited in claim 1. In contrast, Helland does not describe anything about the lead body outer surface. Col. 4, lines 8-10 of Helland merely disclose that the lead is formed of a biocompatible, biostable material. However, nothing in the Helland reference indicates or suggests that the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, as recited in claim 1.

In the Advisory Action, the Examiner asserts that in light of Helland disclosing that the lead body is biocompatible and biostable that "the system of Helland will also be able to form such a layer of blood cells upon implantation and exposure to the bloodstream, as such function is an expected biological reaction to an implanted foreign body." (Page 2 of Advisory Action).

Applicant traverses this rationale. There is nothing in the Helland reference that explicitly or implicitly teaches such subject matter. The Examiner is apparently finding that the subject matter is inherent in the reference. Applicant respectfully disagrees because the Office Action has not established a prima facie case of inherency because, as recited in MPEP § 2112, "In relying upon the theory of inherency, the examiner must provide basis in fact and/or technical reasoning to reasonably support the determination that the allegedly inherent characteristic necessarily flows from the teachings of the applied prior art," citing *Ex parte Levy*, 17 USPQ2d 1461, 1464 (Bd. Pat. App. & Inter. 1990). In this case, the Office Action asserts that the reference lead will be able to form a layer of blood cells. Thus, the Office Action does not even assert that the allegedly inherent characteristic is necessary, let alone provide a basis in fact and/or technical reasoning.

Also, Appellant cannot find in Helland: wherein the outer surface of the ring electrode includes a textured coating including titanium microspheres, as recited in claim 1. Helland does not include or suggest a ring electrode having a textured coating.

The Final Office Action asserts that it would have been obvious "to modify the system as taught by Helland with a ring electrode since such a modification is well known in the medical art for providing the predicable results of providing bi-polar pacing with the tip electrode, pacing multiple sites, or with a ring electrode minimizing thrombosis by not having the ring electrode contacting the vessel wall." (Pages 2-3 of Final Office Action).

However, even if Helland used a ring electrode, there is nothing in the Helland reference to suggest that the ring electrode would be texturized. The Helland reference discusses that the texturizing treatment on the electrode distal tip 60 is to "create a plurality of pore sites and interstitial porosity for chronic ingrowth of tissue." (Col. 6, lines 6-8). Neither the Office Action nor Helland give any indication of a need for such chronic ingrowth of tissue on a ring electrode. Accordingly, there is no reason or suggestion for such a modification of the Helland reference.

Claims 5, 7, 9, and 10 include each limitation of their parent claim and are also not obvious in view of the cited references.

Moreover, regarding claim 7, the Final Office Action states that Helland discusses titanium microspheres "dimensioned to attract circulating blood cells (claims 7, 15 and 18), and trap blood cells (claim 12) (column 5, lines 8-22; column 6, lines 14-17)." (Page 2 of Final Office Action). Appellant traverses this characterization. Column 5, lines 8-22 of the Helland reference discuss the structure and function of the grooves 62 of the Helland electrode tip 60. That reference does not refer to titanium microspheres at all. Column 6, lines 14-17 of the Helland reference states that "particles 70 will have passageway dimensions which allow the passage of red blood cells (typically having a six micron (0.006 mm) diameter) and other blood borne elements. By allowing the migration of red blood cells and other blood carried substances through the interstitial porosity, the events resulting in chronic tissue ingrowth are initiated." Accordingly, it appears this discussion does not relate to trapping blood cells as asserted by the Examiner, but to allowing the passage of blood cells. Reconsideration and allowance is respectfully requested.

Claims 11-16

Appellant believes claim 11 is not obvious in view of the Helland reference since the reference does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the reference: wherein the lead body has a textured outer surface adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface, as recited in claim 11. As discussed above, Helland does not describe anything about the lead body outer surface. Col 4, lines 8-10 merely disclose that the lead is formed of a biocompatible material.

Moreover, Appellant cannot find in the Helland reference: wherein the ring electrode includes an outer textured surface including titanium microspheres, as recited in claim 11. As discussed above, neither the Office Action nor Helland give any indication of a need for such chronic ingrowth of tissue on a ring electrode. Accordingly, there is no reason or suggestion for such a modification of the Helland reference.

Claims 12-16 include each limitation of their parent claim and are also not obvious in view of the cited references.

Moreover, regarding claims 12 and 15, Appellant traverses the characterization of the reference, as discussed above. Reconsideration and allowance is respectfully requested.

Claims 17 and 18

Appellant believes claim 17 is not obvious in view of the Helland reference since the reference does not include or suggest each limitation recited in the claim. For instance, Appellant cannot find in the Helland reference: forming the lead body such that a layer of blood cells is formed on an outer surface of the lead body when exposed to a bloodstream, as recited in claim 17. As discussed above, Helland does not describe anything about the lead body outer surface. Col 4, lines 8-10 merely disclose that the lead is formed of a biocompatible material.

Moreover, Appellant cannot find in the Helland reference: a titanium microsphere outer surface coating on at least a portion of the ring electrode, as recited in claim 17. As discussed above, neither the Office Action nor Helland give any indication of a need for such chronic ingrowth of tissue on a ring electrode. Accordingly, there is no reason or suggestion for such a modification of the Helland reference.

Claim 18 includes each limitation of its parent claim and is therefore also not obvious in view of the cited references. Moreover, Appellant traverses the characterization of the reference, as discussed above. Reconsideration and allowance is respectfully requested.

SUMMARY

It is respectfully submitted that the art cited does not render the claims obvious and that the claims are patentable over the cited art. Reversal of the rejection and allowance of the pending claim are respectfully requested.

Respectfully submitted,

SCHWEGMAN, LUNDBERG & WOESSNER, P.A.
P.O. Box 2938
Minneapolis, MN 55402

Date 12/9/08 By

Peter C. Maki
Reg. No. 42,832

CERTIFICATE UNDER 37 CFR 1.8: The undersigned hereby certifies that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail, in an envelope addressed to: Mail Stop Appeal Brief - Patents Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on this 10 day of December, 2008.

Name

Signature

8. CLAIMS APPENDIX

1. A lead comprising:

a lead body extending from a proximal end to a distal end; and

a ring electrode coupled to the lead body;

wherein the lead body and the ring electrode each have an outer surface adapted to passively prevent formation of clots on the outer surfaces, wherein the outer surface of the lead body is adapted such that a layer of blood cells is formed on the outer surface when exposed to a bloodstream, and wherein the outer surface of the ring electrode includes a textured coating including titanium microspheres.

5. The lead of claim 1, wherein the titanium microspheres have a diameter of between 75-100 μm.

7. The lead of claim 1, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent blood cell layer.

9. The lead of claim 1, wherein the outer surface of the lead does not include any active coatings which elute from the surface to minimize clotting.

10. The lead of claim 1, wherein the lead is adapted to be coupled to a pulse generator and is adapted for delivering cardiac resynchronization therapy.

11. A lead comprising:

a lead body extending from a proximal end to a distal end; and

a ring electrode coupled to the lead body;

wherein the lead body has a textured outer surface adapted to form a layer of blood cells on the outer surface when exposed to a bloodstream so as to passively prevent formation of clots on the outer surface; and

wherein the ring electrode includes an outer textured surface including titanium microspheres.

12. The lead of claim 11, wherein the electrode outer surface is adapted to trap blood cells within the textured surface to form a layer of blood cells on the electrode surface.

13. The lead of claim 11, wherein the titanium microspheres have a diameter of between 75-100 μm.

14. The lead of claim 11, wherein the outer surface of the lead does not include any active coatings which elute from the surface to minimize clotting.

15. The lead of claim 11, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface.

16. The lead of claim 11, wherein the lead is adapted to be coupled to a pulse generator and is adapted for delivering cardiac resynchronization therapy.

17. A lead comprising:

a lead body extending from a proximal end to a distal end;

a ring electrode coupled to the lead body; and

means for passively preventing formation of clots on the ring electrode and the lead body, wherein means for passively preventing clots on the ring electrode includes a titanium microsphere outer surface coating on at least a portion of the ring electrode, and wherein means for passively preventing clots on the lead body includes forming the lead body such that a layer of blood cells is formed on an outer surface of the lead body when exposed to a bloodstream.

18. The lead of claim 17, wherein the titanium microspheres are dimensioned to attract circulating blood cells so as to develop a uniform and tightly adherent biologic surface.

9. EVIDENCE APPENDIX

None.

10. RELATED PROCEEDINGS APPENDIX

None.